

# Neurosurgical Associates of Lubbock

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*Neurosurgical Oncology  
Pediatric Neurosurgery  
Skull Base Surgery  
Spinal Surgery  
Vascular Neurosurgery  
Functional & Stereotactic Surgery*

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Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher Lane, Room 1061  
Rockdale, MD 20852

Re: Docket #97N-484S

Dear Sir:

I have recently learned that you are proposing FDA regulation for allograft bone for use in the medical arena. I am concerned about this regulation. In our neurosurgical practice here in Lubbock, we frequently use allogenic bone for bone grafting in the cervical and lumbar spine. If new regulation impairs our ability to obtain these bone products, we would have severe problems in performing these procedures. which would adversely affect the patients. Bone grafts have been used for a number of years and I believe their safety and efficacy is well established. I am concerned that new regulation could require sponsoring of clinical trials and lengthy regulatory review which could curtail our supply of bone products for an extended period. I would strongly request that you review this upcoming legislation and its effect on the care of our patients.

Richard E. George, M.D.

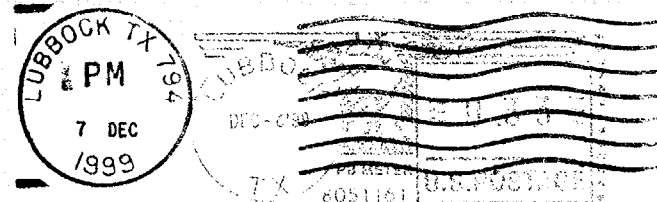
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